

REMARKS

In the Official Action of November 14, 2007, the Examiner rejected claims 14-17 and 19-43 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,922,586 to Davies in view of U.S. Patent No. 7,103,398 to Sieburg. Applicants respectfully traverse the Examiner's rejection for the reasons as set forth below.

As reflected in the claims of the present application, the present invention relates to a method of diagnosing a diseased condition of the skin by placing an electrical conducting probe that contains a plurality of electrodes, each furnished with a number of spikes that are of sufficient length to penetrate the stratum corneum, against a skin surface in a manner not disclosed or suggested by the prior art. While the Examiner recognized that the cited Davies reference does not teach or suggest each electrode being furnished with a number of spikes, the Examiner argued that the electrodes containing spikes were taught by the Sieburg reference. However, contrary to the Examiner's assertions, neither Davies nor Sieburg, either singly or in combination, teach or make obvious the present invention.

Unlike the present invention, Davies relates to a method and system for determining a condition of a selected region of epithelial tissue by using a combination of DC potential measurements and impedance measurements. In particular, according to Davies, the current passing electrodes placed on a surface may pass alternating current through the tissue or epithelium (see column 6, line 49) and the established signal may be measured by the voltage measuring electrodes (see column 6, line 59). However, if the system according to Davies is applied to the skin of the subject, even if the penetration depth can be adjusted by spaced electrodes, so that the current may reach the skin layer beneath the stratum corneum where the most valuable information

about the skin condition can be obtained, the current must still pass through the stratum corneum. It is known though that α -dispersion from the stratum corneum is broad and large and may overshadow impedance data obtained from the skin underneath. As such, the use of the Davies system and method would dilute the results obtained and the diagnosis of the skin condition would therefore be unspecific and not useful.

Additionally, Davies states that the accuracy of the measurements can be enhanced by determining the functional transport alterations in pre-cancerous or cancerous epithelial tissue by applying an agent that may manipulate the tissue while measuring electrical properties. According to Davies, such pharmacological agents may change the electrical activity of diagnosed tissue and give indications whether the tissue is pre-cancerous or cancerous epithelia (see column 6, line 41 and column 7, line 17). However, the method of the agent application introduces an additional degree of complexity in the diagnosis of a skin condition that is not found in the present invention. Moreover, unlike the present invention, when applying the Davies method one must first know whether the examined tissue is abnormal or not before the measurement is made. As such, Davies actually teaches away from the present invention, which discloses a method where high accuracy diagnosis is achieved without applying any agent and without a need of previous knowledge about the tissue condition.

Finally, while Davies also indicates that electrodes penetrating the stratum corneum might be used (column 10, line 58), the reference teaches that this would only be done to decrease impedance and not, as the present invention teaches, to avoid the dispersions caused by the stratum corneum.

Accordingly, the Davies reference is far different than Applicant's claimed invention and does not disclose or make obvious Applicant's claimed features.

Moreover, the Sieburg reference cited by the Examiner also does not disclose or suggest the claimed features, and thus cannot be added to Davies to make the present claims obvious. In particular, Sieburg relates to a method to "generate a pointed portion (34) of the electrode (16)" (see Abstract), and "an array of pointed electrodes and a method of producing the same which are electrically insulated with respect to each other" (see column 7, line 37). Accordingly, measurements performed according to Sieburg, where needle or needle-like electrodes sense a signal separately, will result in high measurement uncertainty originating from a natural variation of skin impedance and may lead to a false diagnosis and depth profile. As such, Sieburg also teaches away from the present invention wherein this problem is avoided in that the spikes are not individually addressed but each electrode contains a plurality of spikes thereby measuring over a large area. The Sieburg reference thus cannot be added to the Davies reference to disclose or make obvious Applicants' claimed invention.

Even further, assuming, *arguendo*, that one of ordinary skill in the art could combine Davies with Sieburg, the combined disclosure still fails to enable one of ordinary skill to practice the invention as claimed. Specifically, a combination of the teaching of Davies and Sieburg would at most lead to a device where individually addressed spikes are used and, in order to more accurately measure the alteration in pre-cancerous and cancerous epithelial tissues, a pharmacological agent may be introduced. However, such, a combination of Davies and Sieburg would entirely fail to teach or in any way make obvious the present claimed invention which comprises a

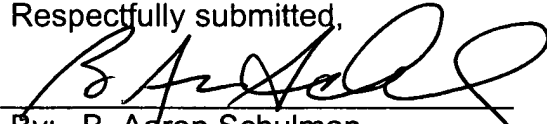
method of diagnosing a diseased condition of the skin by placing an electrical conducting probe that contains a plurality of electrodes, each furnished with a number of spikes that are of sufficient length to penetrate the stratum corneum. Accordingly, it is clear that neither Sieburg nor Davies, either singly or in combination, teach or make obvious the elements claimed and disclosed by the present invention, much less provide one skilled in the art a reasonably apparent reason to combine the two references.

Accordingly, the Examiner's rejection of claims 14-17 and 19-43 under 35 U.S.C. §103(a) on the basis of the cited references is respectfully traversed and should be withdrawn.

In light of the arguments provided herewith, Applicants submit that the present application overcomes all prior rejections and has been placed in condition for allowance. Such action is earnestly solicited.

Date: February 5, 2008

Respectfully submitted,



By: B. Aaron Schulman
Registration No.: 31,877

STITES & HARBISON PLLC ♦ 1199 North Fairfax St. ♦ Suite 900 ♦ Alexandria, VA 22314
TEL: 703-739-4900 ♦ FAX: 703-739-9577 ♦ CUSTOMER NO. 000881